510(k) Summary

k131988

1. Administrative

Device Information

Device Name:	ABL90 Flex
Common Name:	Blood gases (pCO2 and pO2) and blood pH test system
Product Code:	CHL, JGS, CEM, JFP, CGZ, CGA, KHP, GKR, GHS, KQI, JJY, JIX
Device Classification:	21 CFR 862.1120, 862.1600, 862.1345, 862.1170, 864.7425, 864.5620, 862.1145, 862.1665, 862.1150, 864.7455, 862.1660, 862.1450
Classification:	Class II, II, II, II, II, II, II, II, II, II, I (reserved), I (limitation to exemption per 21 CFR 862.9 (c)(9)), respectively.
Classification Panel:	Clinical Chemistry (75) and Hematology (81)
Purpose of submission:	Introduction of a modification that consists of labeling and software changes that suppress glucose results obtained from samples with pO_2 levels below 10mmHg, and to suppress glucose results >270mg/dL obtained from samples with 10mmHg < pO_2 < 25mmHg.

Submitter

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SEP 17 2013

Application Correspondent

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2. Description of Device Modification

The ABL90 FLEX is a portable, automated system intended for in vitro testing of samples of whole blood for the parameters pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, lactate, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO_2Hb, *F*COHb, *F*MetHb, FHHb and *F*HbF).

3. Intended Use

The ABL90 FLEX is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinised whole blood. The ABL90 FLEX is intended for use by

trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting.

4. Indications for use

pH, pO_2 and pCO_2: pH, pCO_2 and pO_2 measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Potassium (cK^+): potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

Sodium (cNa^+): sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.

Calcium (cCa^{2+}): calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Chloride (cCl^-): chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such a cystic fibrosis and diabetic acidosis.

Glucose (*c*Glu): glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Lactate (*c*Lac): The lactate measurements measure the concentration of lactate in plasma. Lactate measurements are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood.)

Total Hemoglobin (*c*tHb): total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

sO_2: oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus reduced hemoglobin.

FO_2Hb: oxyhemoglobin as a fraction of total hemoglobin.

*F*COHb: carboxyhemoglobin measurements are used to determine the carboxyhemoglobin content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

*F*MetHb: methemoglobin as a fraction of total hemoglobin.

*F*HHb: reduced hemoglobin as a fraction of total hemoglobin.

Fraction of Fetal Hemoglobin (*F*HbF): *F*HbF indicates the amount of fetal hemoglobin. *F*HbF is seldom used clinically.

5. Substantial Equivalence

The ABL90 FLEX with the modification described above is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate:

510(k) Number/Device Manufacturer:
K122729 ABL90 Flex, Radiometer Medical ApS

<table>
<tr><th colspan="2">Predicate: ABL90 Flex (K122729)</th></tr>
<tr><th>Similarities</th><th>Differences</th></tr>
<tr><td>Intended Use
The ABL90 FLEX is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinised whole blood. The ABL90 FLEX is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting.</td><td>Modified caution to manual:
Low pO2 levels can influence the linearity of glucose measurements, and can therefore result in falsely low glucose results. Please note that glucose performance is not specified when the pO2 is less than 10 mmHg (1.33 kPa).
The linearity of the glucose is dependent on the oxygen tension of the sample. This dependence is due to the co-reaction of glucose and oxygen by the enzyme glucose oxidase. Low pO_2 levels can influence the linearity of the glucose sensor. The following table outlines the glucose linearity as a function of the pO_2.</td></tr>
<tr><td>Blood Gas Measurement
pH, pO_2, pCO_2 by potentiometry</td><td>Modified information to manual:
<table><tr><th colspan="2">Impact of the pO_2 level on Glucose linearity and specifications of the ABL90 FLEX analyzer</th></tr><tr><td>If the pO_2 level in a sample is:</td><td>Then cGlu linearity specifications only apply to cGlu values between:</td></tr><tr><td><10 mmHg (1.33 kPa)</td><td>Linearity not specified. Glu is not usable.</td></tr><tr><td>$10 \leq pO_2 < 25$ mmHg ($1.3 \leq pO_2 < 3.3$ kPa)</td><td>0.5 – 15 mmol/L (9 – 270 mg/dL)
If cGlu >270 mg/dL, the linearity is not specified and the cGlu value not usable.</td></tr><tr><td>≥25 mmHg (3.3 kPa)</td><td>0.5 - 40 mmol/L (9 – 720 mg/dL)</td></tr></table></td></tr>
</table>

Predicate: ABL90 Flex (K122729)	
Similarities	**Differences**
Electrolyte Measurement cK^+, cNa^+, cCa^{2+}, cCl^- by potentiometry	Software changes: - Suppression of glucose results when pO_2 < 10 mmHg - Suppression of glucose results >270mg/dL when pO_2 is between 10 - 25mmHg - Message: "Glu not usable"
Metabolite Measurement cGlu, cLac by amperometry	
Oximetry Measurement *c*tHb, sO_2 *F*O_2Hb, *F*HHb, *F*COHb, *F*MetHb, FHbF	
Hemoglobin Measurement Spectrophotometry	
Identical Performance Characteristics	
Two-Point liquid calibration	
Menu driven touch screen	
Software operating system Microsoft XPE	
Sample Introduction Aspiration	
Dimensions (length x width x depth)	
External Power Source 230/120 V mains	

6. Design Control Activities

#/ Hazard	Validations and Verifications activities descriptions	Pre-determined Acceptance criteria	Testing results summary	Meet the acceptance criteria or not?
41/Too low Glucose result in the upper reportable range obtained from samples with low pO2 level 48/Unacceptable bias on Glucose results obtained from samples with pO2 levels above 25 mmHg 49/Too low Glucose result in the lower and medium reportable range obtained from samples with low pO2 level	Interference study at different pO_2 levels and at different glucose levels covering the reportable range of the analyser using fresh heparinized whole blood samples.	Bias: ≤10% for glucose when pO_2 is > 10 mmHg when compared to the control	6 different pO_2 levels + pO_2 ≥90 mmHg as control 7 different glucose levels 3 analyzers 6 tests of each sample on each analyzer 2 runs Total of 1512 measurements The results are valid under the conditions that - all glucose results are suppressed when the pO_2 level of the sample is below 10 mmHg, and - all glucose results are suppressed when pO_2 level of the sample is between 10 mmHg and 25 mmHg and the glucose level is above 270 mg/dL all acceptance criteria are met: Bias < 10%	Passed - The acceptance criterion is met under the conditions that all glucose results are suppressed when the pO_2 level of the sample is below 10 mmHg, and - all glucose results are suppressed when pO_2 level of the sample is between 10 mmHg and 25 mmHg and the glucose level is above 270 mg/dL
	Precision study at different pO_2 levels and at different glucose levels representing clinical decision points at low, medium and high glucose.	CV%: ≤ 10%	20 days 3 different pO_2 levels 3 different glucose levels 2 tests of each sample each day 2 runs Total of 2160 measurements The results are valid under the conditions that - all glucose results are suppressed when the pO_2 level of the sample is below 10 mmHg, and - all glucose results are suppressed when pO_2 level of the sample is between 10 mmHg and 25 mmHg and the glucose level is above 270 mg/dL all acceptance criteria are met: CV% ≤ 10%	Passed The acceptance criterion is met under the conditions that all glucose results are suppressed when the pO_2 level of the sample is below 10 mmHg, and all glucose results are suppressed when pO_2 level of the sample is between 10 mmHg and 25 mmHg and the glucose level is above 270 mg/dL

5. Performance Characteristics

Precision

Precision was evaluated according to CLSI guideline "Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition", EP05-A2.

The study was conducted as a 20 day precision study using serum pool sample of glucose. Three levels of glucose have been analyzed in 2 runs per day with 2 replicates for each level.

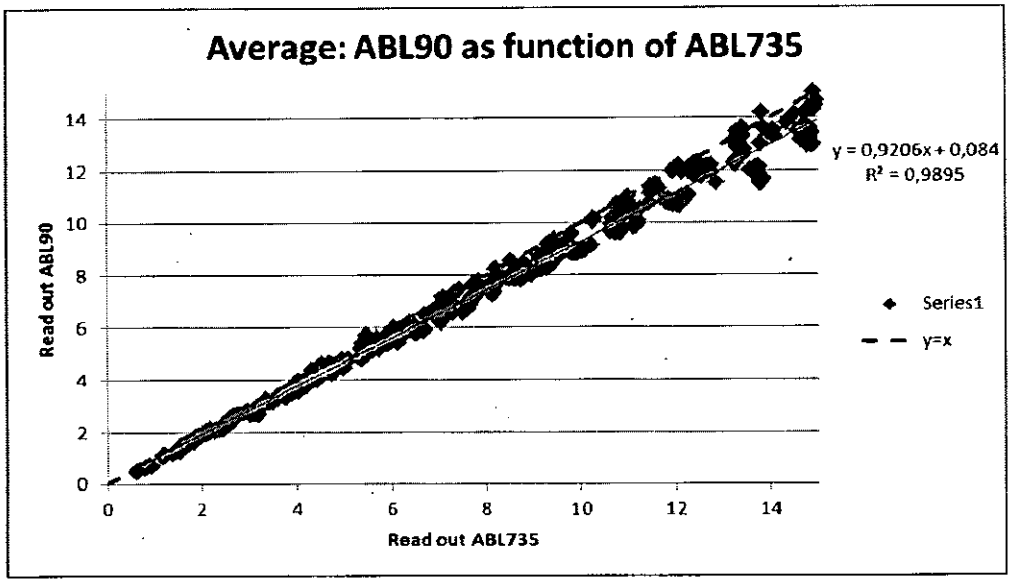
Results of Precision Study:						
		mg/dL				
cGlu level	pO_2 level	Mean	Sr	ST	CV%	n
Glu Low 17.8 ± 2.5 mg/dL	10 mmHg	17.9	0.2	0.8	4.7	240
	30 mmHg	18.0	0.1	0.8	4.3	240
	>90 mmHg	18.1	0.1	0.7	4.1	240
Glu Mid 98.7 ± 9 mg/dL	10 mmHg	101.7	1.1	3.8	3.7	240
	30 mmHg	101.0	0.7	3.3	3.3	240
	>90 mmHg	101.2	0.5	3.3	3.2	240
Glu High 270 ± 6 mg/dL	10 mmHg	254.1	1.6	10.8	4.2	240
	30 mmHg	262.3	1.1	8.8	3.4	240
	>90 mmHg	271.9	1.7	7.4	2.7	240

Method Comparison

Method comparison study versus a comparative analyzer (ABL735) has been conducted according to NCCLS guideline "Method Comparison and Bias Estimation Using Patient Samples", EP09-A2.

This study was an in-house method comparison using untreated donor samples in combination with spiked donor blood where necessary. A total of 52 different donors are used in data mining and approximately 500 samples are measured

Linear regression of the pooled data gives a slope of 0.9206, intercept of 0.084 and an $R^2 \geq 0.95$; fulfilling the requirements to slope (0.9 – 1.1), intercept (0) and correlation coefficient (≥ 0.95)



Interference
Interference study has been conducted according to CLSI guideline "Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition", EP07-A2.

This study evaluates the pO_2 tension in blood samples as an interfering substance to the glucose measurement.

Results of Interference Study							
CV% (X_{TEST} - $X_{CONTROL}$)		pO_2 [mmHg]					
		10	15	20	25	50	80
cGlu [mg/dL]	9	3.3%	3.1%	3.4%	1.1%	3.8%	0.0%
	36	1.3%	1.3%	0.8%	0.5%	0.9%	0.2%
	79	2.0%	1.6%	0.7%	0.8%	0.9%	0.6%
	119	2.0%	1.5%	1.5%	0.9%	1.3%	0.4%
	180	4.7%	2.7%	2.5%	0.9%	0.3%	0.6%
	270	7.0%	6.1%	3.1%	2.4%	2.0%	1.1%
	450	13.6%	9.3%	7.1%	3.8%	5.0%	0.7%

6. Performance Data
The performance data submitted in the original submission (K092686) still apply.

7. Conclusion
The ABL90 FLEX with the modification described above is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate ABL90 Flex (K122729).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 17, 2013

Radiometer Medical ApS
C/O Gitte Juel Friis
Akandevej 21
2700 Bronshoj
DENMARK

Re: K131988
Trade/Device Name: ABL90 Flex Analyzer
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
Regulatory Class: II
Product Code: CHL JGS, CEM, JFP, CGZ, CGA, KHP, GKR, GHS, KQI, JJY, JIX
Dated: June 24, 2013
Received: June 28, 2013

Dear Mr. Friis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k131988

Device Name: ABL90 Flex Analyzer

Indication For Use:

Intended Use:
The ABL90 FLEX analyzer is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate, and oximetry in heparinised whole blood. The ABL90 FLEX analyzer is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting. These tests are only performed under a physician's order.

Indications for use:
pH, pO_2 and pCO_2: pH, pCO_2 and pO_2 measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Potassium (cK^+): potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

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Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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Office of In Vitro Diagnostics and Radiological Health

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Chloride (*c*Cl⁻): chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such a cystic fibrosis and diabetic acidosis.

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Fraction of Fetal Hemoglobin (*F*HbF): FHbF indicates the amount of fetal hemoglobin. *F*HbF is seldom used clinically.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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